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EXAMINER	
GILLIGAN, CHRISTOPHER L	

ART UNIT	PAPER NUMBER
3626	

DATE MAILED: 09/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/872,506	REITBERG, DONALD P.	
	Examiner	Art Unit	
	Luke Gilligan	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 June 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/14/01, 8/26/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 1-17 have been examined.

Claim Objections

1. Claims 11-17 objected to because of the following informalities: Claims 11-13 and 15-17 appear to be inadvertently dependent on claim 9 rather than claim 10. Claim 14 appears to be inadvertently dependent on claim 12 rather than claim 13. Appropriate correction is required.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 1-5 and 8-17 rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The basis of this rejection is set forth in a two-prong test of:

(1) whether the invention is within the technological arts; and

(2) whether the invention produces a useful, concrete, and tangible result.

4. For a claimed invention to be statutory, the claimed invention must be within the technological arts. Mere ideas in the abstract (i.e., abstract idea, law of nature, natural phenomena) that do not apply, involve, use, or advance the technological arts fail to promote the "progress of science and the useful arts" (i.e., the physical sciences as opposed to social sciences, for example) and therefore are found to be non-statutory subject matter. For a process claim to pass muster, the recited process must somehow apply, involve, use, or advance the technological arts.

5. In the present case, claim 1 only recites an abstract idea. The recited steps of merely conducting a drug trial, comparing information, and optimizing tratment does not apply, involve, use, or advance the technological arts since all of the recited steps can be performed in the mind of the user or by use of a pencil and paper. These steps only constitute an idea of how to implement a single patient drug trial and use the results to optimize the patient's treatment.

6. Additionally, for a claimed invention to be statutory, the claimed invention must produce a useful, concrete, and tangible result. Although the recited process produces a useful, concrete, and tangible result, since the claimed invention, as a whole, is not within the technological arts as explained above, claim 1 is deemed to be directed to non-statutory subject matter.

7. In addition, claims 2-5 and 8-17 fail to remedy the deficiencies of claim 1. However, claims 6 and 7 include the feature of assembling the patient population database stored on a computer. Therefore, these claims are deemed to be directed to statutory subject matter.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claim 1 recites the limitation "comparing the information accumulated" at lines 4-5. Since there is no previous recitation of accumulating any information, there is insufficient antecedent basis for this limitation in the claim.

11. In addition, claims 2-17 contain the same deficiencies as claim 1 through dependency and, as such, are rejected for the same reasons.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 1-10, 12, and 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zucker et al., Combining Single Patient (N-of-1) Trials to Estimate Population Treatment Effects and to Evaluate Individual Patient Responses to Treatment (cited in IDS filed 9/14/01) in view of Weinhold et al., A Meta-analytic Model for Integrating Outcomes in Drug Research (cited in IDS filed 8/26/02) and further in view of Kanter et al, International Publication No. WO 98/12669 (cited in IDS filed 8/26/03).

14. As per claim 1, Zucker discloses a method of determining the efficacy of a drug or substance when administered to an individual patient for chronic therapy comprising: a) conducting a single patient, cross-over drug trial of a drug or substance and a placebo in a new patient who is a candidate for treatment with the drug (see paragraph 18); b) comparing information from a comprising a plurality of single patient, crossover drug trials concerning the drug and the placebo with information from the single-patient drug trial of the new patient to aid in the interpretation of the appropriateness of the drug for treatment for the new patient (see paragraphs 17 and 19); and c) optimizing treatment for the new patient by taking at least the action of continuing drug therapy for the new patient using the same drug and dosage regimen

(see paragraph 28). Zucker does not explicitly disclose using the drug trial for predicting the abuse potential of the drug. Zucker also does not explicitly disclose a pre-assembled patient population database comprising drug trial information.

15. Weinhold teaches a drug trial method for determining the abuse potential of a drug including determining various scores representative of the abuse potential of the drug (see paragraphs 3-6 and 9). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the method for determining abuse potential as described by Weinhold with the combined single-patient drug trials of Zucker. One of ordinary skill in the art would have been motivated to make such a combination for the purpose of further aiding in the best selection of appropriate treatment for an individual patient (see paragraph 39 of Zucker).

16. Kanter teaches a patient population database comprising drug trial information from a plurality of drug trials (see page 5, lines 10-30). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate this feature into the method disclosed by Zucker. One of ordinary skill in the art would have been motivated to incorporate this feature for the purpose of providing a user-friendly interface to access information on various drug trials (See page 3, lines 21-28 of Kanter and paragraph 42 of Zucker).

17. As per claim 2, Zucker in view of Weinhold and Kanter teach the method of claim 1 as described above. Zucker further teaches assembling a plurality of cross-over single patient drug trials (see paragraph 18). As described above, Zucker does not explicitly teach assembling a patient population database. However, Kanter teaches assembling a patient population database (see page 5, liens 10-30). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate this feature into the method disclosed by Zucker for the reasons given above with respect to claim 1.

18. As per claim 3, Zucker in view of Weinhold and Kanter teach the method of claim 2 as described above. Zucker further teaches adding the results from the single patient drug trial of the individual human patient to the assembled information (see paragraph 37).

19. As per claim 4, Zucker in view of Weinhold and Kanter teach the method of claim 2 as described above. Zucker does not explicitly teach accumulating the information via the use of the listed objective testing methodologies. Weinhold further teaches accumulating information concerning the abuse potential of a drug via objective testing methodologies that at least includes blood pressure (see paragraph 15). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate this feature into the method disclosed by Zucker for the reasons given above with respect to claim 1.

20. As per claim 5, Zucker in view of Weinhold and Kanter teach the method of claim 2 as described above. Zucker further teaches prescribing said drug for chronic therapy in said patient (see paragraph 28).

21. As per claim 6, Zucker in view of Weinhold and Kanter teach the method of claim 2 as described above. Zucker does not explicitly teach a patient population database stored on a computer. Kanter further teaches said patient population database is stored on a computer (see page 13, lines 24-28). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate this feature into the method disclosed by Zucker for the reasons given above with respect to claim 1.

22. As per claim 7, Zucker in view of Weinhold and Kanter teach the method of claim 6 as described above. Zucker does not explicitly teach a computer database accessible from a remote location. Kanter further teaches said computer database is accessible form a remote location (see page 13, liens 24-28). It would have been obvious to one of ordinary skill in the art

at the time of the invention to incorporate this feature into the method disclosed by Zucker for the reasons given above with respect to claim 1.

23. As per claim 8, Zucker in view of Weinhold and Kanter teach the method of claim 1 as described above. Zucker further teaches adding results from said single-patient drug trial of said new patient to said accumulated information (see paragraph 37). As described above, Zucker does not explicitly teach said scores representative of abuse potential. However, Weinhold teaches such scores (see paragraphs 3-6 and 9). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate this feature into the method disclosed by Zucker for the reasons given above with respect to claim 1.

24. As per claim 9, Zucker in view of Weinhold and Kanter teach the method of claim 1 as described above. Zucker further teaches providing to each patient a test kit containing a supply of said drug, a supply of said placebo, and a questionnaire (see paragraph 18, it is also noted that the crossover referred to in Zucker is between the drug and placebo). As described above, Zucker does not explicitly teach said scores representative of abuse potential. However, Weinhold teaches such scores (see paragraphs 3-6 and 9). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate this feature into the method disclosed by Zucker for the reasons given above with respect to claim 1.

25. As per claim 10, Zucker in view of Weinhold and Kanter teach the method of claim 1 as described above. Zucker does not explicitly teach said drug is selected from the group of those listed. Weinhold further teaches selecting a stimulant, analgesic, and sedative drug (see paragraph 10). It would have been obvious to one of ordinary skill in the art at the time of the invention to apply the method of Zucker to various types of drugs includes those disclosed by Weinhold. One of ordinary skill in the art would have been motivated to apply Zucker in this way for the purpose of accommodating user preferences in the types of drugs that are being tested.

26. As per claim 12, Zucker in view of Weinhold and Kanter teach the method of claim 10 as described above. Zucker does not explicitly teach a narcotic analgesic selected form the listed group. Weinhold further teaches a narcotic analgesic selected form the listed group (see paragraph 10, at least morphine is selected). It would have been obvious to one of ordinary skill in the art at the time of the invention to apply the method of Zucker to various types of drugs includes those disclosed by Weinhold for the reasons given above with respect to claim 10.

27. As per claim 15, Zucker in view of Weinhold and Kanter teach the method of claim 10 as described above. Zucker does not explicitly teach a sedative-hypnotic drug selected from the listed group. Weinhold further teaches a sedative-hypnotic selected form the listed group (see paragraph 10, at least phenobarbital is selected). It would have been obvious to one of ordinary skill in the art at the time of the invention to apply the method of Zucker to various types of drugs includes those disclosed by Weinhold for the reasons given above with respect to claim 10.

28. As per claim 16, Zucker in view of Weinhold and Kanter teach the method of claim 10 as described above. Zucker does not explicitly teach a central nervous system stimulant selected from the listed group. Weinhold further teaches a central nervous system stimulant selected form the listed group (see paragraph 10, at least amphetamine is selected). It would have been obvious to one of ordinary skill in the art at the time of the invention to apply the method of Zucker to various types of drugs includes those disclosed by Weinhold for the reasons given above with respect to claim 10.

29. Claims 11, 13-14, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zucker et al., Combining Single Patient (N-of-1) Trials to Estimate Population Treatment Effects and to Evaluate Individual Patient Responses to Treatment (cited in IDS filed 9/14/01) in view of Weinhold et al., A Meta-analytic Model for Integrating Outcomes in Drug Research (cited

in IDS filed 8/26/02) and Kanter et al, International Publication No. WO 98/12669 (cited in IDS filed 8/26/03) and further in view of Yager et al., U.S. Patent No., 6,180,114.

30. As per claim 11, Zucker in view of Weinhold and Kanter teach the method of claim 10 as described above. Zucker does not explicitly teach a drug for treating hyperkinetic behavior is methylphenidate. Yager teaches selecting the drug methylphenidate (see column 30, lines 50-52). It would have been obvious to one of ordinary skill in the art at the time of the invention to apply the method of Zucker to various types of drugs includes those disclosed by Yager. One of ordinary skill in the art would have been motivated to apply Zucker in this way for the purpose of accommodating user preferences in the types of drugs that are being tested.

31. As per claim 13, Zucker in view of Weinhold and Kanter teach the method of claim 10 as described above. Zucker does not explicitly teach a drug for treating anxiety is a benzodiazepine. Yager teaches selecting the drug type benzodiazepine (See column 30, line 49). It would have been obvious to one of ordinary skill in the art at the time of the invention to apply the method of Zucker to various types of drugs includes those disclosed by Yager for the reasons given above with respect to claim 11.

32. As per claim 14, Zucker in view of Weinhold, Kanter and Yager teach the method of claim 13 as described above. Zucker does not explicitly teach said benzodiazepine is selected from the listed group of drugs. Yager further teaches said benzodiazepine is selected from the listed group of drugs (see column 30, line 49, at least diazepam is selected). It would have been obvious to one of ordinary skill in the art at the time of the invention to apply the method of Zucker to various types of drugs includes those disclosed by Yager for the reasons given above with respect to claim 11.

33. As per claim 17, Zucker in view of Weinhold and Kanter teach the method of claim 10 as described above. Zucker does not explicitly teach a steroid selected from the listed group of

drugs. Yager teaches selecting a steroid from those listed (see column 30, lines 28-36). It would have been obvious to one of ordinary skill in the art at the time of the invention to apply the method of Zucker to various types of drugs includes those disclosed by Yager for the reasons given above with respect to claim 11.

Conclusion

34. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Luke Gilligan whose telephone number is (571) 272-6770. The examiner can normally be reached on Monday-Friday 8am-5:30pm.

35. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571) 272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

36. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

09/19/05

C. Luke Gilligan
Patent Examiner
Art Unit 3626